

**REMARKS**

Claims 1-17 are currently pending in the present Application, following withdrawal of claims 18-49 pursuant to the May 10, 2004 Requirement.

Claims 1-17 stand rejected under § 103(a) as unpatentable over U.S. Patent No. 5,628,960 to Beer, *et al.* ("Beer").

The Pending Rejection: In the pending Office Action, reference is made to the appropriate paragraph of the May 9, 2005 Final Office Action for the teachings of Beer, and it is maintained that while this reference is silent as to removing of filter dust from a partially dried feedstock, this is viewed as a "result effective variable" with well known and predictable results, *i.e.*, that "[r]emoving contaminates prior to drying a feed stock or after drying the feed stock would have had the same expected result of removing the contaminant." November 10, 2005 Office Action at 2-3. The Applicants appreciate the Examiner's further remarks regarding the potential for a Rule 1.132 Declaration to overcome the Beer reference.

The Declaration of Dr. Hans Beer: The Applicants respectfully traverse the pending § 103(a) rejection, and submit the attached Rule 1.132 Declaration of inventor Dr. Hans Beer, Senior Scientist in the research and development department of membrane technology at Sartorius AG (assignee of the present Application), which addresses the reasons why the present invention would not have been obvious to one of ordinary skill in the art possessing knowledge of the cited Beer reference. The Applicants note that as one of the inventors of the invention disclosed in the Beer reference, Dr. Beer is uniquely qualified to

comment on its teachings.

As noted by Dr. Beer, the present invention relates to an improved process for refining the surface of a membrane, and a resulting membrane used to identify specific analytes present in fluid media. As recited in claim 1, the invention involves removal of impurities after the membrane is formed, but before the newly-formed membrane dries. As recited in dependent claim 3, the impurity removal may be conducted by contacting the still-wet membrane with a cleaning agent and/or a cleaning device. Beer Dec. ¶ 3.

As discussed in the present Specification and by Dr. Beer, in the prior art, dust particles formed on membrane structures were minimized, but not eliminated, by measures such as filtration and/or precipitation of impurities from the feedstock liquids prior to the use of the feedstocks in a membrane formation process. These purification processes proved less than completely successful, as the resulting membranes frequently still exhibited dust contamination, and impurities interfered with the membranes' ability to provide crisp, well-defined target analyte indications. The precipitation/purification processes also added significant additional expense to membrane production. Beer Dec. ¶ 4.

The cited Beer reference is noted to be an example of this prior art, wherein cellulose derivatives to be used with the polymeric blend solution are re-precipitated prior to the addition of the polymeric blend solution and prior to the formation of a membrane. As Dr. Beer notes, this reference does not suggest to one of skill in the art the concept of removing impurities after formation of the membrane, but before all the solvent has been evaporated, in the manner of the

present invention. Beer Dec. ¶ 5.

In response to the assertion that the order of contaminant removal steps is optimization of a “result effective variable” (*i.e.*, the removal of contaminants prior to drying a feedstock would have had the same expected result as in Beer reference in removing contaminants), Dr. Beer states that based on his knowledge and years of experience in the field, this new process and resulting product is a completely new approach to membrane production that was not obvious to those of skill in the art. Beer Dec. ¶ 6. Specifically, Dr. Beer notes that it is not correct that removing contaminants prior to drying vs. after drying results in the same product. Dr. Beer maintains, based on his years of experience as a senior researcher in the field, that:

- one of skill in the art would know that the nature and order of steps in the prior art *has been dictated by the product obtainable by the prior art technology*, not as a result of mere choice of the order of interchangeable process steps;
- one of the primary reasons for using a feedstock purification process is that it is not possible to completely remove filter dust from a fully dried membrane using a conventional process such as brushing;
- the deficiencies of the post-membrane formation cleaning technologies force manufacturers to make their feedstocks as pure as reasonably possible to minimize the dust load on the finished membrane;
- one of skill would know that complete removal of dust has been difficult to achieve by physical action (*e.g.*, brushing), as physical processes applied to dry membranes result in undesirable damage to the membrane surface, and in particular irregular grooves in the membrane surface which degrade the membranes’ ability to provide definitive analyte results (the damaged, non-uniform or homogeneous surface resulting in a turbulent front of a migrating analyte fluid, and asymmetry in migration which and render the sample results indistinct).

Thus, Dr. Beer notes that the order of the prior art steps was dictated by the need to minimize dust formation on the final dried product, and that the best the

prior art could achieve was a contaminated membrane, unlike the essentially dust-free membrane obtained with the present invention. Beer Dec. ¶¶ 8-9.

Dr. Beer next rebuts the suggestion that reordering the process steps would have been obvious to one of ordinary skill, stating that *the common expectation of those skilled in the art would be that there is no way dust could be removed from a partially-dried, crude membrane without destroying the membrane*. Beer ¶ 10. Thus, the present invention represents a radical shift away from the common expectation in the art, and not a mere re-ordering of interchangeable process steps. *Id.* Dr. Beer further notes that, despite the great motivation to find and implement an improved membrane production process (in order to eliminate the significant additional expense associated with prior art feedstock purification methods, and provide a much cleaner membrane product, and thus a more useful analytical tool), no one had previously pursued the present invention's approach. Beer ¶ 11. The Applicants submit this is strong evidence that the present invention is not the result of mere "optimization of a result effective variable," else these cost savings and improved product would have appeared in the market long ago.

Finally, Dr. Beer presents information regarding unexpected results, *i.e.*, that one of ordinary skill in the art knowledgeable of conventional filter dust removal techniques, would not have expected that mere rearrangement of process steps would result in the present invention's significantly lower cost, highly clean membrane with such a highly uniform test fluid migration (phenol red solution) of 90 seconds/40 mm, while maintaining a precise and intensive

colored dividing line. Beer Dec. ¶ 12.

In view of the Dr. Beer's comments regarding the state of the art, the expectations of those of skill in the art, and the other evidence of non-obviousness (such as the lack of pursuit of the present invention, despite great economic and technical motivation to do so), the Applicants respectfully submit that one of ordinary skill would not have found the present inventive process and resulting membrane to be an obvious development from the cited Beer reference. Accordingly, reconsideration and withdrawal of the pending rejection based on this reference is respectfully requested.

#### CONCLUSION

The Applicants respectfully submit that claims 1-17 are allowable over the Beer reference. Early and favorable consideration and issuance of a Notice of Allowance for claims 1-17 is respectfully requested.

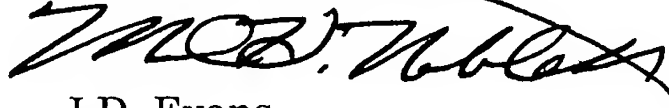
If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response. Please charge any such fee or any deficiency in fees, or credit any overpayment of fees,

to Deposit Account No. 05-1323 (Docket 010743.50685US).

February 10, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J.D. Evans", written over a horizontal line.

J.D. Evans

Registration No. 26,269

Mark H. Neblett

Registration No. 42,028

CROWELL & MORING, LLP  
P.O. Box 14300  
Washington, DC 20044-4300  
Telephone No.: (202) 624-2500  
Facsimile No.: (202) 628-8844